No. 20-1110

IN THE

Supreme Court of the United States

SANDOZ INC., *et al.*
Petitioners,

v.

IMMUNEX CORP., *et al.*
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF *AMICI CURIAE* FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AND AMERICA'S HEALTH INSURANCE PLANS, INC. IN SUPPORT OF PETITIONERS

JEFFREY K. FRANCER
KARIN HESSLER
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Ave., NW
Suite 850
Washington, DC 20001

JULIE SIMON MILLER
THOMAS M. PALUMBO
AMERICA'S HEALTH INSURANCE PLANS, INC.
601 Pennsylvania Ave., N.W.
South Building, Ste. 500
Washington, D.C. 20004

MATTHEW S. HELLMAN
Counsel of Record
LAUREL A. RAYMOND
JENNER & BLOCK LLP
1099 New York Ave., NW
Washington, DC 20001
mhellman@jenner.com
(202) 639-6000

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

OTHER AUTHORITIES

INTEREST OF THE *AMICI CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic medicines constitute 90% of all prescriptions dispensed in the United States, yet account for only 20% of total medicine spending. AAM regularly participates in litigation as *amicus curiae*.

America's Health Insurance Plans, Inc. ("AHIP") is a national association whose members provide coverage for health care and related services to millions of Americans every day. These services improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. Increases in prescription medicine prices are a leading driver of rising health care costs. AHIP is committed to practical solutions that reduce consumer costs and increase patient access to needed medication, so AHIP has a strong interest in ensuring that claims of patent

---

[1] Pursuant to Rule 37.6, no counsel for any party authored this brief in whole or in part, nor did any party or counsel for a party make a monetary contribution to fund the brief's preparation or submission. Counsel of record for all parties received timely notice of and consented in writing to this filing.

invalidity are resolved efficiently and effectively. AHIP regularly participates in litigation as *amicus curiae*.

Amici and their members have a significant interest in the issues raised by the petition: namely, ensuring that a patentee may not exploit formalisms to circumvent the basic rule that an inventor may obtain only one patent for an invention. The decision below provides a playbook for brand-name medicine companies to unlawfully extend their monopolies and deprive patients and taxpayers of less expensive generic and biosimilar alternatives. The American public will likely pay *billions* of dollars in higher costs just to obtain the particular medicine implicated in this case. And, absent review by this Court, other medicine patentholders are sure to follow the roadmap endorsed by the Federal Circuit's decision. *Amici* urge this Court to grant certiorari to reaffirm and ensure that medicine patentholders cannot unlawfully extend their monopolies and deprive patients of lower cost generic and biosimilar alternatives.

INTRODUCTION AND SUMMARY OF ARGUMENT

There is hardly a more basic or important rule of patent law than that an inventor is entitled to a single patent for an invention. A central corollary to that rule is that a patentholder cannot obtain a patent claim on an obvious variant of an existing claim. The obviousness type double-patenting ("ODP") doctrine has long extended both to instances in which a patent-holder applies for such a patent, and where it acquires a patent. Put simply, a patentholder cannot evade the ODP doctrine by acquiring an obvious patent claim via an

assignment. These limits are critical to a well-functioning patent system in general. But they are particularly important in the context of patents on medicines where any gamesmanship by patentholders can so directly impact patients and public health by keeping low-cost generics and biosimilars off the market, impeding access on an individual level as well as burdening already scarce healthcare resources.

The ODP doctrine's protections have now been undermined by a Federal Circuit decision that will be immensely costly to American patients and taxpayers absent review by this Court. Although the panel majority maintained the prohibition on the *assignment* of obvious patents, it blessed a *licensing* arrangement that gave respondents ("Immunex") all substantial rights to an obvious variant. As the dissent recognized, the panel decision allows Immunex to leave the "licensor" with commercially valueless rights in exchange for an extended "license" to practice patent claims that are patentably indistinct from previously-issued claims. The decision offers an end-run around the rules against ODP, and a roadmap for companies seeking to extend their monopolies beyond their lawful term.

Absent review by this Court, little stands in the way of other companies applying respondent's blueprint to their own expiring patents. Immunex's extended patent term means that manufacturers, like petitioners ("Sandoz"), must wait another decade before they can provide patients and healthcare systems with lower-cost alternatives to Immunex's product. In the employer-sponsored coverage market, employers, their health insurance providers, and enrollees could have saved

nearly $1 billion in 2018 alone had petitioner's low-cost alternative been able to come to market after the expiration of the earlier-expiring Immunex patents covering the etanercept protein. If the decision below stands, this tale will be told and retold for other medicines as generic and biosimilar alternatives are kept off the market. As explained below, the Federal Circuit decision is particularly likely to be used to improperly extend exclusivities for biologic medicines. Those medicines can rest upon hundreds of patents, any one of which could be extended to block biosimilar alternatives. Biosimilars already face substantial difficulties coming to market from these patent estates. The maneuver approved by the decision below will only make those estates larger. And the losers will be the American public, which will be wrongfully deprived of lower-cost medicines due to patent term prolongation based on otherwise non-patentable variations to patents that have already expired.

Certiorari is warranted to prevent these costs from recurring and to ensure that ODP correctly "polices the proper application of the patent term for each invention." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005).

ARGUMENT

I. Review Is Warranted Because The Decision Below Misapplies ODP And Provides A Roadmap For Perpetuating Patent Monopolies.

Patent law contains a fundamental balance to secure innovation: "[p]atents endow their holders with superpowers, but only for a limited time." *Kimble v. Marvel Ent., LLC.*, 576 U.S. 446, 451 (2015). This Court

has long policed the risk double patenting presents to this bargain. *See, e.g.*, *id.* (explaining the Court has "carefully guarded" the exclusivity cut-off date); *Miller v. Eagle Mfg. Co.*, 151 U.S. 186, 198 (1894) (collecting cases and explaining that "no patent can issue for an invention actually covered by a former patent, especially to the same patentee, although the terms of the claims may differ."). ODP ensures that a patentee receives one period of exclusivity for an invention—a period they cannot extend through subsequent patent claims covering obvious variations of the invention. Pet. App. 10a-11a; *see also Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1384 (Fed. Cir. 2010). Yet here, Immunex has obtained double patented claims in everything but name, and has nonetheless received the blessing of the Federal Circuit to extend their period of exclusivity another ten years.

A. Immunex's Rights Under The Parties' "License" Make It The Functional Owner Of The Patents-In-Suit.

Immunex invented etanercept,the active ingredient in Enbrel. By Enbrel's 1998 launch, Immunex had sought and obtained patent protection for its invention. Pet. App. 6a-7a. Enbrel has enjoyed a patent monopoly ever since, though that protection should have ended five years ago when Immunex's patents on the etanercept protein expired.

To avoid losing its monopoly, Immunex acquired via a "license" the applications underlying the patents-in-suit from co-plaintiff and competitor Roche. Pet. App 38a-39a. Initially, these patents covered a protein that was similar to—but distinct from—etanercept. *Id.*

After taking over prosecution of the applications, however, Immunex re-directed the claims to cover etanercept—subject matter that is patentably indistinct from Immunex's now-expired patents ("the Reference Patents"). *Id.*

Immunex's license gives it all the hallmarks of ownership over the patents-in-suit. As the panel decision acknowledges, Immunex has the sole right to practice the patents-in-suit. Pet. App. 7a-8a. It also has exclusive rights to grant sublicenses and has first right to rectify any suspected patent infringements. *Id.* Perhaps most crucially, Immunex has complete control over prosecution of the patents-in-suit, allowing Immunex to mold the claims to cover etanercept. *Id.* The rights to use, enforce, and exclusively prosecute a patent are the key factors for determining who owns contested intellectual property. *See, e.g.*, *Alfred E. Mann Found. for Sci. Rsch. v. Cochlear Corp.*, 604 F.3d 1354, 1360-61 (Fed. Cir. 2010); *Vaupel Textilmaschinen KG v. Meccania Euro Italia S.P.A.*, 944 F.2d 870, 874-75 (Fed. Cir. 1991). In short, by virtue of its rights under the licensing agreement, Immunex is the "common owner" of both the patents-in-suit, and the Reference Patents, and thus the ODP doctrine should have barred Immunex from extending its monopoly from the latter to the former.

B. The Decision Below Misapprehends The Extent To Which Roche Retains Any Meaningful Control Over The Patents-In-Suit.

The panel majority agreed that the ODP doctrine would apply if Immunex possessed "all substantial rights" in the patents-in-suit. Pet. App. 12a, 16a, 24a.

But it concluded that Immunex did not in fact possess all substantial rights, notwithstanding Immunex's undisputed rights discussed above: the rights to exclude competition, assert the patents, collect damages for infringement, and practice the patents free of any royalty obligation. According to the panel, Immunex did not possess all substantial rights because Roche retained a secondary right to sue for infringement and a right to veto an Immunex assignment. *Id.* at 21a-22a.

Those two rights, however, are quintessentially *insubstantial*—indeed, they are commercially valueless. Start with Roche's secondary right to sue for infringement. The panel decision makes much of that right, but it is illusory. As the dissent explains, under the license, Roche must give 180 days' notice to Immunex before it sues for infringement, and Immunex has the right during that period to provide a royalty-free license to the would-be infringer. Pet. App. 41a. In other words, Roche can exercise its "right" to sue if and only if Immunex, having been apprised of Roche's intentions, does not cut that right off by granting a license. A right that Immunex can nullify is no right at all, and certainly not a substantial one.

So too with Roche's supposed veto power over Immunex's right to assign its rights. Whatever heft that right might have in other contexts, it is an insubstantial one here. Under the parties' agreement, Immunex has the absolute right to convert the license to an assignment for $50,000, and thereby extinguish Roche's right to veto a subsequent assignment (and also extinguish Roche's secondary right to sue for that matter). Immunex purchased all the other rights it

possesses in the patents-in-suit for *$45,000,000*, which means that Roche's residual $50,000 right is *de minimis*. *Cf. Vaupel*, 944 F.2d at 875 (concluding that a more onerous restriction on transfer—an outright veto power—was nothing more than a "minor derogation from the grant of rights"). The all *substantial* rights doctrine is meaningless if parties can evade it by structuring their deal to include *de minimis* payments. Indeed, in this case, $50,000 residual right is not just *de minimis*, but outright illusory. Roche was willing to convert the license to an assignment for *$0*; it was *Immunex* that insisted upon the $50,000 contingency. Pet. App. 40a-41a. Rights that concededly have no commercial value are, by definition, insubstantial.

C. The Formalistic Decision Below Provides Clear Instructions For Future "Licensees" To Extend Their Monopolies Indefinitely.

The panel's formalistic approach to ODP ensures that Immunex will not be the last patentee to attempt this gambit. The panel decision provides a blueprint for patentees interested in extending their monopolies past their scheduled expirations. Without a firm statement from this Court that such gamesmanship will not work, brand-name medicine patentees will be gifted a new strategy in their evergreening playbooks.

To understand the risk posed by the panel's decision, note that for a price equal to approximately 2% of *one year's* worth of revenues from etanercept,[2] Immunex

[2] Immunex earned $1.9 billion in revenue from etanercept in 2004 alone, Pet. App. 41a, and paid just $45 million for its license extending its monopoly for an additional 15 years.

obtained a "license" that allows it to extend its patent monopoly fifteen years past its scheduled expiration. If the Federal Circuit's decision stands, nothing prevents other brand-name medicine manufacturers from evading the protections against unjustifiably extending patent monopolies precisely as Immunex has done here. A patentee can simply take over substantially all rights to a patent application from another party, while leaving that party with nominal rights to posture the transaction as a license rather than assignment. The patentee will then have a patent application that is immune from ODP, and like here, can mold the claims and obtain a prolonged patent term for its product based on otherwise patentably indistinct variations of the original patent's claims.

To avoid ODP, the patentee can characterize its patent acquisition as a license by, say, leaving the competitor with nominal rights that will not compromise the patentee's unfettered control over the patent application. The patentee would be sure to acquire an exclusive right to prosecute the newly-obtained patents, as Immunex did here. Armed with that powerful tool, the patentee could continually file new applications on minor, obvious variations of its invention, with each new patent extending the monopoly further into the future.

The majority decision below is particularly likely to be deployed to extend monopolies for a category of medicines known as biologics. Biologics are comprised of complex combinations of sugars, proteins, or nucleic acids, and they can rest on *hundreds* of underlying patents that cover the medicines' various components as well as the methods of manufacturing and using those

components. Kevin T. Richards, et al., Cong. Rsch. Serv., R46221, *Drug Pricing and Pharmaceutical Patenting Practices* 26-27 (2020), https://fas.org/sgp/crs/misc/R46221.pdf (explaining that biologics manufactured by AbbVie (Humira), Johnson & Johnson (Remicade), and Biogen/Genentech (Rituxan) rest on hundreds of patents and that other companies are considering adopting this patenting practice). These patent estates already delay manufacturers from launching biosimilar competitors to brand-name medicines. AAM Biosimilars Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients* at 5 (2019), https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf. Allowing other biologic manufacturers to prolong patent terms as Immunex has done here adds yet another layer biosimilar manufacturers must navigate before bringing cost-saving competition to the market.

In the proceedings below, Immunex argued that their loophole is inconsequential because revisions in the patent laws supposedly make similar gamesmanship difficult. Response to Petition for Rehearing en Banc at 19, ECF No. 113. This is not so. The Federal Circuit has *already* considered other cases concerning doubled pre- and post- reform patents, indicating that Immunex's loophole is hardly "sui generis," as they claim. *Id.; see, e.g., Novartis Pharm. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355 (Fed. Cir. 2018) (considering the expiry terms of duplicate pre- and post-GATT patents). The patent regime Immunex exploited still governs an enormous number of patents. If a brand-name company uses the Immunex blueprint to extend *even one* of those

patents beyond its scheduled expiration—a simple enough prospect given the panel's decision here—brand-name companies will be able use the panel's interpretation of the all-substantial-rights test to block these cheaper alternatives from coming on the market. This prevents patients from obtaining lower-cost generics, at great cost. The extended monopoly on Enbrel alone has cost consumers and the American medical system billions of dollars.

II. The Decision Below Means More Expensive Medicines for Patients Who Need Them Most.

The panel decision was not only wrong, but its consequences are also quite real. Immunex now retains a patent monopoly over etanercept for an additional decade, during which it will undoubtedly continue to charge high prices for Enbrel, a medicine critical for treating rheumatoid arthritis. The biosimilar alternative will not be available to patients, driving up costs for everyone through higher medicine prices and higher insurance premiums. This Court's review is needed to prevent the American healthcare system from incurring potentially billions in unwarranted costs for a medicine that has already benefited from over two decades of patent protections.

Generic and biosimilar medicines are affordable alternatives to brand-name medicines. According to research by Barclays, biosimilar medicines are anywhere between 20% and 60% cheaper than their brand-name peers. *See* Barclays Bank PLC, Biosimilars Monthly: Mar 2020 Edition at 11 (Mar. 21, 2020). Those affordable prices have made biosimilars some of the most popular medicines on the market. By the average

biosimilar's fourth year of sales, it will have captured nearly 40% of the market for that medicine. *Id.* Biosimilars stand to reduce direct spending on biologics anywhere from $24 to $150 *billion* between 2017 and 2026, depending on industry and regulatory decisions. Andrew W. Mulcahy, Jakup P. Hlavka, and Spencer R. Case, *Biosimilar Cost Savings in the United States*, RAND Health Quarterly (2018), https://www.rand.org/pubs/periodicals/health-quarterly/issues/v7/n4/03.html. Generic medicines are similarly critical to affordable healthcare. Over the last 10 years, generic medicines have been responsible for nearly *$2.2 trillion* in healthcare system savings in the United States. AAM, *Generic Drugs and Biosimilars Secure Big Savings for U.S. Patients* (2020), https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generic-Drug-Biosimilars-Savings-US-Fact-Sheet.pdf.

Those numbers stand in stark contrast to the prices for brand-name medicines like Immunex's Enbrel, which provides a useful case study in the costs of extended exclusivity. Since its 1998 debut, Immunex has raised the price of Enbrel *almost 500%*, earning the company over $5 billion in revenues in 2019 alone. Adam Feurstein, *Amgen Indulges in Another Rheumatoid Arthritis Drug Price Increase*, The Street (May 5, 2015), https://www.thestreet.com/investing/amgen-indulges-in-another-rheumatoid-arthritis-drug-price-increase-13139368; Lauren Steele, *The Most Expensive Drugs of 2019*, Singlecare: The Checkup (Dec. 10, 2019), https://www.singlecare.com/blog/most-expensive-drugs-2019/; *Amgen Reports Fourth Quarter And Full Year 2019 Financial Results*, Cision (Jan. 30, 2020), https://www.prnewswire.com/news-releases/amgen-reports-fourth-

quarter-and-full-year-2019-financial-results-300996505.html. Unsurprisingly, those prices have caused a significant burden on the U.S. healthcare system. "Between 2012 and 2016, total Medicare and Medicaid spending on Enbrel increased 129% and a total of $7.7 billion of taxpayer funds were spent on the drug." I-MAK, *Overpatented, Overpriced Special Edition: Enbrel* at 4, http://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf.

Additionally, during that same period, "the average annual Medicare spending on Enbrel per person (the annual price of the drug) nearly doubled from $16,828 to $32,891." *Id.* Research conducted by AHIP shows that in 2018 alone over 100,000 individuals enrolled in employer-sponsored health coverage used Enbrel at a cost of nearly $4 billion. It is estimated that had an Enbrel biosimilar been available, employers, their insurers, and enrollees could have realized nearly $1 billion in savings in 2018. Cumulatively, this means that billions of dollars in inflated costs have been borne by consumers as a result of Immunex's conduct. The result is that patients must pay more—either out of pocket or through higher insurance premiums—for medication covered by patents that should have expired years ago.

It did not have to be this way. If Sandoz's etanercept-based biosimilar, Erelzi, had hit the market in 2016 when it was first approved, it could have saved the US healthcare system hundreds of millions, if not billions of dollars, by now. Assuming, conservatively, that it captured only 10% of the etanercept market and provided only a 20% price discount compared to the brand-name Enbrel, Erelzi would have saved the U.S.

healthcare system $101 million in its first year of sales alone. Moreover, the availability of lower-cost Erelzi would have expanded patient access to the medicine they need, while leaving more money in the pockets of those who depend on etanercept for treatment. Instead, Immunex was able to extend its monopoly for fifteen years past its scheduled expiration.

***

Immunex has nearly completed its end-run around the patent system. By acquiring its dubious "license" from Roche, Immunex has extracted billions of additional dollars from patients and payers that it would not have otherwise earned had a lower-cost alternative been available. In the process, they and the decision below have created a map for other brand-name medicine patentees to do the same. The end result undermines the protections against ODP and could potentially cost Americans tens of billions of dollars in healthcare costs. This Court should grant certorari and prohibit this gamesmanship.

CONCLUSION

Amici respectfully request that the Court grant the petition for certiorari.

Respectfully submitted,

Jeffrey K. Francer
Karin Hessler
ASSOCIATION FOR ACCESSIBLE MEDICINES
601 New Jersey Ave., NW
Suite 850
Washington, DC 20001

Julie Simon Miller
Thomas M. Palumbo
AMERICA'S HEALTH INSURANCE PLANS, INC.
601 Pennsylvania Ave., N.W.
South Building, Ste. 500
Washington, D.C. 20004

Matthew S. Hellman
Counsel of Record
Laurel A. Raymond
JENNER & BLOCK LLP
1099 New York Ave., NW
Washington, DC 20001
mhellman@jenner.com
(202) 639-6000

Counsel for Amici Curiae